DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 6 2002

Daniel A. Kravoc
Counsel to Lona Inc.
Patton Boggs LLP Attorneys at Law
2550 M Street, NW
Washington, DC 20037-1350

Re: Docket No. 75N-183H/CP14

Dear Mr. Kracov:

This is in reference to your citizen petition (CP14) dated May 15, 2002, filed under Docket No. 75N-183H in the Dockets Management Branch. The petition requests that FDA reopen the administrative record to allow for the submission and evaluation of additional data supporting the safety and efficacy of benzethonium chloride in topical antimicrobial drug products for over-the counter (OTC) healthcare professional and consumer use.

The procedures governing the review of citizen petitions are set out in regulations found at 21 CFR 10.30. The regulations provide, among other things, that the Commissioner shall furnish a response to a petition within 180 days of the petition, agency resources and priorities permitting. See 21 CFR 10.30(e). This is to advise you, pursuant to 21 CFR 10.30(e)(2), that because of the existence of other priorities, the agency is unable to provide a response to the petition at this time.

If you have any questions regarding this matter, please refer to the docket and comment numbers noted above and submit all inquiries to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, Maryland 20852.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

75N-183H

LET 32

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 11-6-02

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 75N-183H

TO: Dockets Management Branch, HFA-305

[X] The attached material should be placed on public display under the above referenced Docket No.

[X] This material should be cross-referenced to Comment No. CP14

Charles J. Ganley, M.D.

Attachment